Llywodraeth Cymru
Welsh Government

Novel coronavirus (COVID-19)

Asymptomatic testing for health workers; roll out of lateral flow devices

Standard Operating Procedure

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Reference Documents

ID	Document	Version
[1]	NHS England & Improvement Publications reference 001559	2
[2]	Next Steps for Reducing Nosocomial Transmission of COVID-19 Infection in Welsh Hospitals and Care Homes - briefing paper 15th November 2020	
[3]	Briefing paper: Asymptomatic testing of frontline NHS staff and others with contact with patients in Wales using lateral flow devices 25th November 2020	
[4]	https://nwssp.nhs.wales/covid-19-information/covid-19-death-certification-central-hub1/notification-to-public-health-wales/	
[5]		
[6]		

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1. Overall Aim

Following advice provided by Welsh Government nosocomial transmission group, the aim of this SOP is to roll out regular testing of all asymptomatic public-facing health workers using lateral flow assay devices (LFDs) on nasal swab sample from 14 December 2020. This, together with RT-PCR tests, will provide an integrated testing approach to meet the key objectives.

2. Key Objectives

The key objectives will be to:

- Protect staff and the vulnerable people they care for.
- Support NHS and other health services with the control of virus spread and their risk reducingstrategy.
- Reduce staff COVID-19 absenteeism.
- Support both COVID-19 and non COVID-19 care pathways

3. Background

Proposal from Nosocomial Transmission Group on 15th November 2020 was expanded to public-facing health workers. This followed a pilot in NHS England (NHSE) of 1,200 staff members in five NHS trusts, which demonstrated the feasibility and acceptability of regular testing of staff members with lateral flow devices. This was undertaken as a comparative technology assessment including to RT-PCR.

Asymptomatic staff testing

The purpose is to identify health workers who are COVID-19 test positive and pose a risk ofinfection to the vulnerable patents they care for.

Routine asymptomatic testing will increase the number of staff requiring to self-isolate. While this is in large part positive, wider harm may occur when services cannot be provided, but this effect will rapidly diminish as infected staff are identified.

Lateral flow tests are less sensitive than RT-PCR tests overall, and are only likely to give a positive result for individuals who have a high viral load on the swab that is collected. This tends to correlate to the detection of infection in those who are highly infectious, so these tests are less likely to return positive results from non-infectious individuals (those in either the very early or later stages of an infection). A positive LFD test will require a follow up test by RT-PCR (as outlined in section 6). Due to the lower sensitivity of the LFD tests, false negatives are more common than with RT-PCR, so lateral flow tests are only advised for asymptomatic individuals, who have a lower initial likelihood of infection and would not otherwise be tested.

This testing programme is voluntary, but staff should be strongly encouraged to take part to help keep their workplace safe for the people they care for, visitors and all their colleagues

4. Lateral flow antigen testing

Lateral flow antigen testing detects the presence of the COVID-19 viral antigen from a swab sample. LFDs are handheld devices, which produce results within 30 minutes, and they can be self-administered.

The approach using lateral flow antigen testing is as follows

- Based on testing characteristics such as sensitivity and modelling data, testing of health workers using the lateral flow antigen device will take place twice weekly, using self-administered nasal swabbing (with confirmation of positives by RT-PCR by the local designated COVID-19 laboratory)
- Once a member of staff has seen the training video, they are deemed competent.
- A digital reporting solution is now available via www.gov.uk/report-covid19-result
- Symptomatic staff and other staff working in vulnerable areas, or who are participating in studies such as SIREN, should continue their current method of testing and will access RT-PCR testing in line with local guidance and/or study protocols

5. Methodology

The following are key elements of the rollout which are either provided nationally or determined locally.

Frequency of testing

Modelling of the benefits of routine staff testing by the Centre for Mathematical Modelling of Infectious Diseases at the London School of Hygiene and Tropical Medicine concludes that LFDs administered every three days may prevent 54% of transmission compared to 52% with RT-PCR tests taken every five days, assuming that all people self-isolate upon symptom onset or receipt of a positive result. The model takes account of the different test performances of LFDs and RT-PCR tests, and assumes LFDs provide results (and thereby the institution of isolation) within 30 minutes of sample collection, compared to 1.3 days for RT-PCR tests. The sensitivity of LFDs is much higher for detection of people with a high viral load, who are by implication those who are most infectious, than for those with a low viral load.

To mitigate this, the number and impact of false negatives can be reduced through repeat testing, and with greater effect with more frequent repeat testing, and the impact of false positives can be reduced by follow up RT-PCR tests.

Table: Modelling of impact of testing in populations with different COVID-19 prevalence

Specificity (%)	Sensitivity (%)	Prevalence (%)	PPV	Positives from 1,000 tests			NPV	Negatives from 1,000 tests		
				Total positive results	True positives	False positives		Total negative results	True negatives	False negatives
99.6	50	0.01	0.01	4	0	4	1.00	996	996	0
		0.05	0.06	4	0	4	1.00	996	996	0
		0.1	0.11	4	1	4	1.00	996	995	1
		1	0.56	9	5	4	0.99	991	986	5
		5	0.79	19	15	4	0.98	981	966	15
		10	0.93	54	50	4	0.95	946	896	50
99.6	90.2	1	0.69	13	9	4	1.00	987	986	1

Specificity and sensitivity of LFDs

The LFDs have a very high specificity of 99.6%, but a much lower sensitivity of between 50% and 70% (relative to RT-PCR). LFDs are more likely to detect people with a high viral load who are by implication those who are most infectious. To mitigate the lower sensitivity, the number and impact of false negatives can be reduced through repeated testing, and the impact of false positives can be reduced by follow up RT-PCR tests.

Lateral flow device provision

The manufacturer's instructions for use (IFU) are included in the box and are detailed and very technical.

We have provided separate guidance on how to self-administer the test and interpret the results. This separate guidance should be provided to everyone who is self-testing. Local information will need to be provided on, for example, numbers to call for any queries related to the use of devices and reporting and outcome of results.

Storing LFDs

The kit should be stored at room temperature or in a cool dry place (2°C to 30°C). Do not leave in direct sunlight or store in a fridge or freezer. If the kit has been stored in a cool area (less than 15°C), leave it at normal room temperature for 30 minutes before using. **Keep the test kit away from children**.

Testing public-facing asymptomatic staff

Staff should test twice weekly every three to four days to fit in with shift and leave patterns. For example Wednesday and Sunday, or Monday and Thursday. The test should be carried out in good time before a shift to allow the shift to be covered by alternative staff if the test is positive (e.g. the night before a morning shift or the morning before an afternoon shift). You will need to wait 30 minutes after taking the test to find out the results. Please make sure you have a smartphone or other means to read and record your results in 30 minutes.

6. Reporting of results and RT-PCR testing

The results from the device will be recorded by the staff member after 30 minutes. The timing is critical, as leaving the test for longer can lead to false positive results and the test will need to be repeated. Results should be recorded in line with the following.

- Negative: The presence of only the control line (C) and no test line (T) within the result window indicating a negative result.
- Positive: The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicating a positive result. The presence of any test line (T), no matter how faint, indicates a positive result.
- Invalid result: If the control line (C) is not visible within the result window after performing the test, the result is considered invalid.

When an invalid result is observed, the test will be repeated with a new test kit.

The individual will need to upload the result whether it is positive/negative/invalid via the www.gov.uk/report-covid19-result. The positive result will be fed into the CRM to ensure contact tracing will be commenced.

Follow up RT-PCR test

If an individual tests positive on an LFD they are advised to self-isolate and book a follow up PCR test. Ideally this test should be taken within 24 hours of the LFD.

A follow up RT-PCR test is advised as it is processed at a laboratory and enables samples to be genomic sequenced for any variants of concern and also monitor any changes in the nature of the virus.

- **If the RT-PCR test is also positive** the individual remains in self-isolation for a period of ten days from the date of the original LFD test.

- **If the RT-PCR test is negative and taken within 24 hours of the LFD** the individual and their contacts are no longer required to self-isolate.

- **If the RT-PCR test is negative but was taken more than 24 hours after the original LFD** the individual and their contacts must remain in self-isolation for the full 10 days from the date of the original LFD. This is because the time between the two tests was too long to be confident that the positive LFD was incorrect.

If a person does not take up a follow up RT-PCR test they will be required to self-isolate for 10 days.

If a person has tested positive with an LFD or an RT-PCR test and had to self-isolate for 10 days they are advised not to take further tests for a 90 day period (unless new symptoms develop). Staff members will need to liaise with their organisation to track the date at which the retesting should start.

Staff can either book an RT-PCR test through local arrangements or via the www.gov.uk/get-coronavirus-test

Advice for safe disposal of lateral flow test waste
If the test is negative

- Drain any remaining reagent into sink or toilet.
- Place lateral flow test kit into the domestic waste bag (normally a “black” bag).
- Do not place the test into any recycling waste streams.

If the test is positive

- Drain any remaining reagent into sink or toilet.
- Place the lateral flow test kit into a secure bag and keep this in a safe place for 72hrs. After this time place in the domestic waste bag (normally a “black bag”)
- Do not place the test into any recycling waste streams.

As you are a COVID-19 positive individual in self isolation from this point, then you are required to ensurethat waste that has been in direct contact with you is held for 72 hours before entering the domestic waste stream.

As set out in the manufacturer’s safety instructions, the buffer solution is not hazardous; however, if accidentally ingested, a medical practitioner should be informed.

If any of the items in the boxes of devices supplied are missing, broken or damaged, if the device is damaged or breaks during use, if the user of the test has any concerns about the performance of the test, or if any adverse incident with the test occurs, then these incidents should be reported. Organisations should report this information to the Medicines and Healthcare products Regulatory Agency (MHRA) via their reporting portal: www.coronavirusyellowcard.mhra.gov.uk.

7. Training

The training video (described below) and information leaflet describing ‘how to self-test’ will be sufficient for staff to become proficient in self-testing independently. Some staff, where English is not their first language, or who have dexterity or other issues, will require practical support which may include hands-on demonstrations/training.

It is possible that some members of staff may not be willing or able to use the device. All organisations will need to establish a local helpline/drop-in location to assist staff with queries which they may have with the use of the device, and to support with further training if necessary. An eLearning for health workers video is available https://learninghub.nhs.uk/self-swab which can be used to support training the trainers. Written instruction materials and FAQs have been made available nationally

8. Implementation

The rollout commenced in the week of 14th December 2020 with two phases:

Pathfinder phase

There was an initial pathfinder phase for four weeks, prior to full rollout from the week of 11 January 2021.

Full rollout phase

The aim of this phase will be for organisations to ensure that all staff they identify for this programme commence testing.

Review and Integration

Regular review of processes and information and integration of new improvements (such as digital solution for recording).

Logistics

Organisations will need to provide national TTP programme leads with details of delivery addresses for supplies and have adequate room for storage. An internal distribution location will be required for issue of devices to all (eligible) staff members, reporting template, printed copy of the instruction guide and any other written instructions including local information.

In addition, each organisation will need to:

- Ensure staff have seen the training video
- Establish a help line or drop-in assistance point for staff members having difficulty performing the self-administered test
- Ensure staff are aware of the need to report their result via www.gov.uk/report-covid19.result
- Provide information for staff members on what to do if they test positive and where they will get their swab test for follow up RT-PCR and to remind them they do not need to self-test with the LFD for 90 days after any positive result is confirmed by RT-PCR
- Local reporting arrangements should be followed

Key risks

This is not an exhaustive list but includes:

Test limitations:

- Failure to follow the instructions for test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results. In addition to watching the training video, some staff may require further assistance to familiarise themselves with self-testing.
- A false negative test result may occur if the specimen was collected poorly, or extracted from the swab incorrectly. A negative test result will not eliminate the possibility of SARS-CoV-2 infection. Theinstruction booklet is clear that, if the staff member has returned a negative result but is symptomatic, they should follow government guidelines and obtain a RT-PCR swab test.
- Positive or negative test results do not rule out co-infections with other pathogens and therefore staffmembers may also have other respiratory infections such as Influenza A or B. Also, COVID-19 infection may develop after a test is performed, prior to the next screening test. Participating in the screening programme therefore does not obviate the need for appropriate infection control precautions to be maintained.
- Lateral flow devices may not detect non-infectious virus during the later stages of viral shedding that might be detected by RT-PCR molecular tests. Hence, they will not detect staff members who are recovering from having had the virus.

These limitations will be mitigated, as far as possible, by the actions outlined in this document, particularly related to training, simple written instruction materials and with an organisational help line, and by other nationally and locally available information on COVID-19 symptoms and actions.

1. Appendix 1 – Staff Reporting Form Example

Although the pathfinder phase is complete, and a digital reporting solution is now available, the following reporting form may support health organisations with putting in place local arrangements for recording test results and monitoring usage of the test devices.

Full Name:	Mary Davies
Job/Role	Occupational Therapist
Service/Department/Ward/Team	Integrated Health and Social care team
Line Manager	Jane Thomas

	Date of test/s performed	Time Test performed	Lot number on test strip	Result (recorded as positive, negative, invalid)	If Invalid confirmation that a repeat test has been performed	Comments
1	15/12/20	08.15	ZX445BT675	Negative		First test observed by trainer
2	18/12/20	07.00	Zx445bt676	Invalid	Yes	
3	18/12/20	07.00	Zx445bt677	Negative		
4	21/12/20	07.30	Zx445bt678	Negative		
5	25/12/20	05.15	Zx445bt679	Negative		
6	28/12/20	7.45	Zx445bt680	Positive		Line manager informed as working tomorrow and RT-PCR test booked
7						
8						
9						
10						

2. Appendix 2 – Organisation Information

Notification to Public Health Wales – https://nwssp.nhs.wales/covid-19-information/covid-19-death-certification-central-hub1/notification-to-public-health-wales/

Registered medical practitioners in England and Wales have a statutory duty to notify their local authority or local Health Protection Team of suspected cases of certain infectious diseases. It is vital that staff upload their results via the https://www.gov.uk/report-covid19-result, so that contact tracing can be undertaken. A positive lateral flow test result must also be followed at the earliest opportunity by a follow up RT-PCR test, which will be reported to Public Health Wales.

COVID-19 is listed in the prescribed list of Diseases notifiable to local authority proper officers under the Health Protection (Notification) Regulations 2010:
http://www.legislation.gov.uk/uksi/2010/659/contents/made

In Wales, Public Health Wales (PHW) will be automatically notified of all COVID-19 positive swab results bythe reporting laboratory. The test is a RT-PCR lab based test.

- The follow up RT-PCR test will be the reportable test through to PHW.

Organisation Information Requirements

A digital solution to register the test devices and upload test results has been introduced to support organisations in moving from the pathfinder phase to full rollout of the programme to their public-facing staff.

The Welsh Government aim is for all organisations to use the portal (https://www.gov.uk/report-covid19-result).